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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,229	04/27/2006	John William Chapman	056159-5261	6003
9629 7590 10/02/2007 MORGAN LEWIS & BOCKIUS LLP		EXAMINER		
1111 PENNSYLVANIA AVENUE NW			STEADMAN, DAVID J	
WASHINGTO	N, DC 20004		ART UNIT PAPER NUM	
		<b>'</b>	1656	
			MAIL DATE	DELIVERY MODE
			10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)		
		10/539,229	CHAPMAN ET AL.		
	Office Action Summary	Examiner	Art Unit		
		David J. Steadman	1656		
Period fo	The MAILING DATE of this communication app or Reply	pears on the cover sheet with the	correspondence address		
A SH WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  36(a). In no event, however, may a reply be to will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDON	N. timely filed must be mailing date of this communication. IED (35 U.S.C. § 133).		
Status					
1)⊠	Responsive to communication(s) filed on 27 A	<u>pril 2006</u> .			
2a)[_	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.				
3) 🗌	Since this application is in condition for allowar				
	closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 4	453 O.G. 213.		
Disposit	ion of Claims				
5)	Claim(s) <u>1-13</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed.  Claim(s) is/are rejected.  Claim(s) is/are objected to.  Claim(s) <u>1-13</u> are subject to restriction and/or of	wn from consideration.			
Applicat	ion Papers	•	•		
10)	The specification is objected to by the Examine The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	epted or b) objected to by the drawing(s) be held in abeyance. Stion is required if the drawing(s) is o	ee 37 CFR 1.85(a). bjected to. See 37 CFR 1.121(d).		
Priority (	under 35 U.S.C. § 119				
12) [ a)	Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  1. Certified copies of the priority document  2. Certified copies of the priority document  3. Copies of the certified copies of the priority document  application from the International Bureau  See the attached detailed Office action for a list	s have been received. s have been received in Applica rity documents have been receiv u (PCT Rule 17.2(a)).	ition No ved in this National Stage		
Attachmen		_			
2)	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date	4) Interview Summal Paper No(s)/Mail   5) Notice of Informal 6) Other:	Date		

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## **DETAILED ACTION**

## Status of the Application

- [1] Claims 1-13 are pending in the application.
- [2] Applicant's preliminary amendment to the claims and specification, filed on 6/16/05, is acknowledged.
- [3] Applicant's preliminary amendment to the specification, filed on 4/27/06, is acknowledged.
- [4] Receipt of an information disclosure statement, filed on 6/16/05, is acknowledged.
- [5] Receipt of a substitute Declaration under 37 CFR 1.63, filed on 4/27/06, is acknowledged.
- [6] Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, and an amendment directing entry of the sequence listing paper copy into the specification, all filed on 4/27/06, is acknowledged.

## Lack of Unity

[7] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or goups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I**, claim(s) 1-9 and 12-13, drawn to the special technical feature of a method for producing a type III antifreeze protein in a fungal host cell that is deficient in protein glycosylation.

**Group II**, claim(s) 10-11, drawn to the special technial feature of a composition comprising recombinant AFP type III, wherein from about 50-99% of the AFP is unglycosylated.

The technical feature linking the inventions of Groups I-II is an unglycosylated AFP protein. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason(s):

According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions listed as Groups I-II do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group II is recombinant AFP type III, wherein from about 50-99% of the AFP is unglycosylated, which is shown by Chao et al. (*Prot. Sci.* 2:1411-1428, 1993) to lack novelty or inventive step because the reference teaches an AFP type III protein recombinantly produced in *E. coli* (see *e.g.*, p. 1425). As evidenced by the prior art reference of Mosmann (US Patent 4,690,893), *E. coli* does not glycosylate proteins (column 8, line 42) and as such, the protein of Chao et al. would be "about 99%" unglycosylated. Thus, the shared same or coresponding special technical feature of Groups I-II is not a contribution over the prior art.

[9] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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[10] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Notice of Possible Rejoinder

[11] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

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and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J. Steadman, Ph.D. Primary Examiner Art Unit 1656